

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Pepicelli et al.

Serial No: 09/394,020

Filed: September 10, 1999

For: Regulation of Lung Tissue by  
Hedgehog-Like Polypeptides, and  
Formulation and Uses Related Thereto

Art Unit: 1646

Attorney Docket No. HUIP-P01-032

Examiner: J. Andres

Assistant Commissioner for Patents  
Washington, DC 20231

TECH CENTER 1600/2900

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**Declaration Under 35 U.S.C. §1.132 of Carmen Pepicelli***(Cons. and  
11/10/01)*

Sir:

I, Carmen Pepicelli of Lowell, Massachusetts, hereby declare as follows:

1. I am an employee of Curis, Inc., which licenses the above-described application from The President and Fellows of Harvard College, the assignee of record.
2. Experiments were performed in collaboration with me, the results of which are depicted in Exhibits A-E, which demonstrate the effects of treating embryonic lung cultures with a hedgehog antagonist. Exhibit A shows by in situ hybridization that the expression of the downstream mediator of *hedgehog* signaling, *gli-1*, decreases during later lung development. Exhibit B shows the inverse relationship between the expression of *gli-1* and the expression of the lung maturation marker, Sp-C. Exhibit C shows that treatment of embryonic lung cultures with *hedgehog* antagonist XX decreases *hedgehog* signaling as demonstrated by a substantial decrease in *gli-1* expression. Exhibit D shows that *hedgehog* antagonist XX increases the expression of the maturation marker Sp-C. Exhibit E shows that in contrast to embryonic lung cultures treated with a hedgehog antagonist, embryonic lung cultures treated with a *hedgehog* agonist have increased surfactant production.
3. The above experiments were performed in accord with the teachings of the abovementioned patent application.
4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are

punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Carmen Pepicelli

Dated: 9/0/01

Signature:

